3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
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3M ESPE

K070956

MAY 22 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:	3M ESPE Dental Products
Street:	3M Center
ZIP-Code, City:	St. Paul, Mn 55144
Country:	USA
Establishment Registration Number:	2110898
Official Correspondent:	Karen O'Malley Sr. Regulatory Specialist
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E-mail:	kdomalley@mmm.com
Date:	March 09, 2007

Name of Device

Proprietary Name:	SEA2
Classification Name	Resin tooth bonding agent 21 C.F.R. §872.3200 as a Class II device.
Common Name:	Dental Adhesive

Predicate Devices

Device	510(k)
Adper Single Bond Plus	K962785
Adper Prompt	K060684 K040857 K020946
Clearfil SE Bond	K023842 K012442 K990040

Description and Technology Equivalence

SEA2 Self-etch adhesive is classified as Resin tooth bonding agent (21 C.F.R§872.3200) because it is a device intended to be applied to the interior of a prepared cavity of a tooth to improve retention of restorative materials (compomer and composite restorative material). SEA2 is also indicated for intraoral repairs of composite resin, porcelain or metal using light-cured composite resin. SEA2 can be used to seal dentinal tubules of hypersensitive teeth and exposed root surfaces to treat dentinal hypersensitivity.

SEA2 Self-etch adhesive is a simple to use, two-bottle, self-etch bonding adhesive with bottle A containing the aqueous primer and bottle B containing the acidic adhesive. This delivery design is common to many of the predicate devices as noted in the submission. The primer contains a color indicator which indicates complete coverage of the preparation. The color disappears upon addition of the adhesive, indicating activation of the acid and insuring that a proper etch is taking place.

Substantial safety and comparative performance testing of SEA2 has been conducted. The chemical composition is similar to predicate self-etch adhesive devices. The data provided in this 510(k) submission shows that the composition is safe based on the biocompatibility assessment conducted based on ISO10993 and ISO 7405.

The performance testing includes adhesion to dentin and enamel. The test results provided in the submission confirm the performance as substantially equivalent to the predicate devices with common indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2007

Ms. Karen O'Malley
Sr. Regulatory Specialist
3M ESPE Dental Products
3M Center
St. Paul, Minnesota 55144-1000

Re: K070956
Trade/Device Name: SEA2 Self Etch Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: March 30, 2007
Received: April 05, 2007

Dear Ms. O'Malley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Print Form

Indications for Use

510(k)Number: K070956

Device Name: SEA2 Self Etch Adhesive

Indications For Use:

1. Bonding between dentin/enamel and composite filling materials

2. Bonding between dentin/enamel and compomer filling materials

3. Intraoral repair of porcelain, composite, and metal using light-cure composite resin.

4. Desensitization of hypersensitive teeth, root surface desensitization

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K070956